



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 29-50255

April 20, 2000

Gerben F. Leyendekker
Gerben Leyendekker Dairy
8517 Avenue 360
Visalia, California 93291-8943

WARNING LETTER

Dear Mr. Leyendekker:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of an illegal drug residue in a cow that originated from your dairy. As a follow-up to USDA's finding, our investigator performed an inspection of your dairy operation located in Visalia, California, on March 16 through 21, 2000. The inspection revealed violations of Section 402 and 501 of the Federal Food, Drug, and Cosmetic Act (the Act).

On February 7, 2000, you sold a cow, identified with back tag number [REDACTED] (USDA laboratory report number 281485), for slaughter as human food at [REDACTED]. [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of the drug penicillin in the liver at 0.40 parts per million (ppm), and in the kidney at 0.65 ppm. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle (Title 21 Code of Federal Regulations, Part 556.510). Your use of penicillin in a dairy cow resulted in the illegal drug residue found in the liver and kidney. A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

You lack an adequate system for determining the medication status of animals you offer for slaughter. Your medication records do not contain the dosage administered and the individual performing the medication of each animal at your dairy.

You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling or your veterinarian's prescription labeling.

You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Re-Covr brand of tripeleennamine hydrochloride within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Your veterinarian's prescription labeling specifies the drug is to be used in the treatment of mastitis and downer cows with a dosage of 15 to 20 cubic centimeters (cc) per cow. Your practice of administering 25 to 30cc to treat slow moving cows is not in conformance with your veterinarian's prescription.

Failure to comply with the label instructions on drugs you use to treat your cows and calves presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

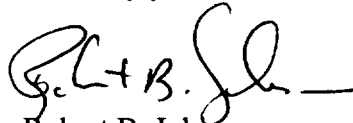
You have established a history of offering animals for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of January 13, 1988, through February 7, 2000, you sold thirteen cows and calves for human food which were found to contain illegal drug residues. During this same period you sold seventeen calves which were found to be CAST positive due to the possible presence of harmful levels of antibiotics. As a result of the violative residues, the FDA conducted inspections of your dairy on May 6 and 7, 1991, September 12, 1996, June 6, 1997, and on March 16 through 21, 2000. During

each of these inspections you were warned that it is illegal to market animals with illegal levels of antibiotics. As a result of violations found during two of those inspections you were sent Warning Letters on August 6, 1991, and October 22, 1996. Also, USDA sent you a letter for each instance in which their analysis found violative levels of drug residues. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made.

Please direct your reply to Suzanne Schenck, Compliance Officer.

Sincerely yours,

A handwritten signature in black ink, appearing to read "G. L. + B. Johnson", followed by a horizontal line.

Robert B. Johnson
Acting Director, San Francisco District

cc:

A large, solid black rectangular redaction mark covering several lines of text.